

REMARKS

This submission is in response to the Official Action dated August 10, 2004. Claims 58, 60, 62-71 and 89-101 are currently pending. Reconsideration of the above-identified application, in view of the following remarks, is respectfully requested. Each of the Examiner's rejections is discussed below.

Rejections under 35 U.S.C. §102(e)

The Examiner has rejected claims 58, 60, 68-71 and 89-101 as allegedly anticipated under 35 U.S.C. §102(e) by Fujiwara (U.S. Patent No. 6,071,866). Specifically, the Examiner contends that Fujiwara discloses liquid skin cleanser comprising a biguanide polymer, a metallic material, and other components, such as lactic acid and surfactants, and Fujiwara performs tests to assess antimicrobial activity. The Examiner further states that, because the Fujiwara composition would inherently form a moisture-resistant film, the claims are anticipated.

However, Fujiwara is not a valid §102(e) reference. Fujiwara was filed June 6, 2000, after the filing date of the current invention, (Sept. 9, 1999), and cannot be used as a §102(e) reference. The Fujiwara patent claims priority to two patents, U.S. Patent No. 5,681,802 filed June 1, 1994 and U.S. Patent No. 5,914,300 filed Feb. 25, 1997. Both of these patents were filed before the current application, and if available as priority documents to Fujiwara, would provide an early enough date to make Fujiwara available under §102(e). However, neither priority document can be used to anticipate any claims of the current invention.

The '802 and '300 patent documents disclose compositions where cationic polymers are useful moisturizers (see '802 Example 1). A particular antimicrobial agent, chlorhexidine (CHX; 1,6-di(4'-chlorophenyl-diguanido)hexane) is also disclosed. However, chlorhexidine is a small molecule having two guanido groups and a molecular weight of 540 g/mol; it is not a biguanide polymer. Neither the '802 nor the '300 patents mention biguanides or biguanide polymers. Since neither priority reference mentions biguanides polymers, the Fujiwara patent cannot obtain either priority filing date for an invention involving biguanide polymers. Although Fujiwara does disclose one

particular biguanide, poly(hexamethylene biguanide) hydrochloride (see col. 8), it cannot be used as §102(e) art for compositions or uses comprising biguanide polymers since Fujiwara was filed after both the provisional priority documents and the non-provisional application disclosing the presently claimed invention.

Additionally, Fujiwara teaches the addition of 6 to 30% surfactant. Surfactants reduce the surface tension of the water and therefore reduce the water resistance of the composition and substantially reduce or eliminate the ability of the composition to form a moisture-resistant film. The moisture-resistant film, which is formed in practicing the current invention, is not an inherent aspect of Fujiwara, and therefore the claims would not be anticipated even if the reference were valid.

For the above reasons, reconsideration and withdrawal of all of the Examiners rejections under 35 U.S.C. §102 is respectfully requested.

Rejections under 35 U.S.C. §103(a)

The Examiner has rejected claims 58, 60, 62-71 and 89-101 as obvious under 35 U.S.C. §103(a) by Fujiwara (U.S. Patent No. 6,071,866) in view of Sawan et al. (WO 95/17152) and Smith (U.S. Patent No. 5,576,006). Specifically, the Examiner contends that, although Fujiwara fails to disclose a silver salt or a water-insoluble organic to cause cross-linking of PHMB, Sawan teaches that crosslinking PHMB with a water-insoluble organic compound enhances the final activity, and that the use of silver salts may be used as a bactericidal metallic material. Further, the Examiner contends that Smith provides the state of art for preparing topical PHMB-containing lotions.

The rejection under 35 U.S.C. §103(a) is invalid for the same reason the 35 U.S.C. §102(e) rejection is invalid. Fujiwara can not be used as a §103(a) reference for the present invention involving the use of biguanides polymers since it can not use the priority dates provided by the parent applications. Fujiwara was filed after the application date of the current invention and cannot be used as a §103(a) reference.

Further, for a claim to be obvious under 35 U.S.C. § 103(a), three criteria must be satisfied: (i) there must be some suggestion or motivation to combine or modify the cited references, (ii) there must be a reasonable expectation of success of combining or modifying the cited references, and (iii) the combined references must teach each and every limitation of the claimed invention. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25 (Fed. Cir. 2000) (internal citations omitted); see also MPEP § 2142.

The metal materials, as taught by Fujiwara, are used as surfactants. These materials include alkali metal and alkaline earth metals (see col.6, line 24-25). The use of silver or other noble metals is not disclosed, and there is no teaching that suggests a modification from the alkali or alkaline earth metal to a noble metal has a reasonable expectation of success. There is no motivation in either reference to replace the metal ion surfactant disclosed in the cleaning formulation with a silver salt. The fact that silver salt is known to have antimicrobial properties is irrelevant to its moisturizing capability. Without a motivation to combine, the claims of the current invention are not obvious over this combination of references.

The claims listed in the present submission are therefore unobvious over the combination of Fujiwara and the '152 and '006 publications, and reconsideration and withdrawal of this rejection is therefore respectfully requested.

Double-Patenting

All claims have been rejected by the Examiner under the judicially created doctrine of obviousness-type double-patenting as being allegedly unpatentable over various claims in commonly-owned U.S. Patents 6,180,584; 6,030,632; 5,869,072; and 5,817,325.

Upon indication of allowable subject matter in the present application, the allowable subject matter not being patentably distinct from the claims of one or more of the above-cited patents, an appropriate terminal disclaimer will be timely filed.

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Therefore, in view of the above remarks, it is earnestly requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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